REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-28 and 31-59 are in the application. Through this amendment, claims 28, 32-34, and 38 have been amended, while claims 29 and 30 have been cancelled. Claims 11-18 presently stand withdrawn in view of a previous election.

In the Official Action, the Examiner rejected claims 1, 9-10, 19, 26-28, 36-38, 48-50 and 58-59 on the grounds of non-statutory obviousness-type double patenting as being allegedly unpatentable over claim 1 of U.S. Patent No. 5,752,942 and claims 1, 3, 11, 12 and 18 of U.S. Patent No. 6,629,963.

In response, attached hereto are terminal disclaimers relating to U.S. Patent No. 5,752,942 and to U.S. Patent No. 6,629,963. With the filing of these terminal disclaimers, it is respectfully submitted that the obviousness-type double patenting rejection has been overcome.

The Examiner rejected claims 1-8, 19-25, 28-35 and 38-47 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. (U.S. Patent No. 3,071,135). The Examiner asserted that "Baldwin et al. meets the claim limitations as described above except for a needle

inner and outer diameter, cannula thickness, and bevel planar angle ranges as claimed by Applicant and syringe barrel." The Examiner asserted that it would have been obvious to obtain these features.

Baldwin et al. is directed to a hollow needle. The needle includes a beveled front face 12 which includes beveled side faces 13. A heel surface 15 is also provided. (Col. 3, ll. 12-16). The heel surface 15 is "dished" to define a depression or recess 17, as clearly shown in Fig. 3. (Col. 3, ll. 41-50).

Claim 1 is directed to a syringe assembly which includes a needle cannula "having a multi-beveled point including a plurality of planar bevels extending at different angles relative to said central axis, including a primary bevel, a pair of tip bevels and a pair of middle bevels". In contrast, Baldwin et al. does not provide at least five planar bevels in its device. As clearly shown in Fig. 3, the recess 17 is dished and not formed planar. Also, the shape of the heel 15 about the recess 17 is unclear, as well as, of the shape of the beveled side faces 13. In any regard, at least five planar surfaces are not shown or disclosed in Baldwin et al. Moreover, there is no suggestion or motivation to modify Baldwin et al., since the recess 17 must be dished. (See, col. 3, ll. 41-50).

It must be noted that the specific claimed beveled configuration has been found by Applicants to provide a needle that requires less penetration force which, thus, causes less pain to be experienced by a patient. (See, paras. [0010] - [0012] of Applicants' specification). The claimed beveled structure provides a very beneficial and tangible result over the prior art and is not the result of optimization or other obvious determinations. It is respectfully submitted that claim 1, along with dependent claims 2-8, are patentable over Baldwin et al.

Claim 19 is directed to a syringe assembly which includes a needle cannula having a multi-beveled point "comprised of a primary bevel, a pair of tip bevels, and a pair of middle bevels" wherein "said planar angles of said primary bevel and said pair of middle bevels are substantially equal." There is no disclosure or suggestion in Baldwin et al. of what angles are to be used in forming the side faces 13, the heel 15, or the recess 17. As such, there is no disclosure or suggestion of having a planar angle for at least three different bevels be substantially equal (i.e., the planar angle of a primary bevel plus the planar angle of a pair of middle bevels). Again, as indicated above, the claimed bevel configuration provides a meaningful benefit which is non-obvious. It is respectfully submitted that claim 19, along with dependent claims 20-25, are patentable over Baldwin et al.

Claim 28 is directed to a syringe assembly which includes a needle cannula having a multi-beveled point "comprised of five bevels, wherein each of said five bevels is provided on said cannula at a planar angle defined between said central axis and a reference plane" and "wherein each of said five bevels is provided on said cannula at an angle of rotation about said central axis". Further, "a first planar angle is defined at said bevel corresponding to a first rotational angle, a second planar angle is defined at said bevel corresponding to a second rotational angle, said first and second rotational angles being different with said first and second planar angles being substantially equal." Baldwin et al. does not provide such an arrangement. Both portions of the heel 15 are located at the same rotational angle relative to a central axis, while both side faces 13 are also located at the same rotational angle relative to the central axis. As discussed above, there is no disclosure in Baldwin et al. of planar angles. Even taking that both of the side faces 13 may be formed at the same planar angle or that both of the heel portions 15 about the recess 17 may be formed at the same planar angle, both side faces 13 and both heel portions 15 are at the same, not different, rotational angle relative to each other; there is no disclosure or suggestion in Baldwin et al. to have bevels at two different rotational-angle locations with the same planar angle. In other words, there is no disclosure or suggestion to have two or more of a side face 13, a heel portion 15, and/or recess 17 at the same planar angle. It is respectfully submitted that claim 28, along with dependent claims 29-35, are patentable over Baldwin et al.

Claim 38 is directed to a syringe assembly which includes a needle cannula having "first, second, third, fourth and fifth bevels bounding" an opening defined through a first end of the needle cannula. The bevels are arranged in a specific contiguous sequence "wherein said first and third bevels each have a greater length than each of said second bevel, said fourth bevel, and said fifth bevel." Baldwin et al. fails to disclose such an arrangement. With the specific claimed contiguous sequence, two bevels must be separated by a bevel of shorter length with those separated bevels being also greater in length than two other formed bevels. With respect to Baldwin et al., it can be argued that portions of the heel 15 about the recess 17 have greater length than the recess 17. However, the side faces 13 clearly have greater length than the heel portions 15. Claim 38 would require Baldwin et al. to have heel portions 15 with greater length than the side faces 13. It is respectfully submitted that claim 38, along with dependent claims 39-47, are patentable over Baldwin et al.

The Examiner rejected claims 50-57 under 35 U.S.C. §103(a) as being allegedly unpatentable over De Luca (U.S. Patent No. 3,308,822).

De Luca is directed to a hypodermic needle which includes multiple facets. As shown in Fig. 10, open end of the lumen 14 is bound by a front face 12 and two planar faces 13 and 16.

As such, there are three bevels bounding the open end 14. The front face 12 is located furthest from the pointed tip of the device.

Claim 50 is directed to a syringe assembly which includes a needle cannula having a plurality of discrete bevels "wherein one of said plurality of discrete bevels is located furthest from said point and has a length shorter than any of said other ones of said plurality of discrete bevels." In contrast, De Luca provides a bevel having the greatest length, not the shortest length, at a location furthest from the tip of the device. There is no disclosure or suggestion in De Luca to provide otherwise. It is respectfully submitted that claim 50, along with dependent claims 51-57, are patentable over De Luca.

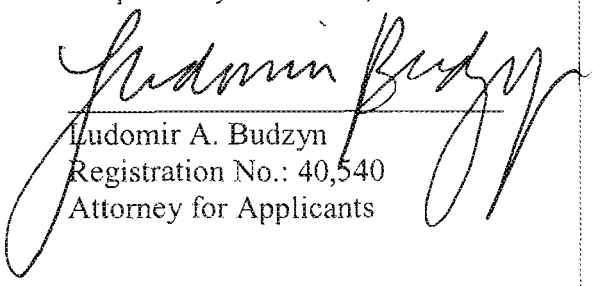
The Examiner rejected claims 9-10, 26-27, 36-37, 48-49 and 58-59 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. or De Luca in view of Hausser (U.S. Patent No. 5,385,555). The Examiner asserted that Baldwin et al. or De Luca meet the claimed limitations "except for a needle shield with a specific Shore hardness's [sic] as claimed." The Examiner cited needle shield 36 of Hausser as allegedly overcoming this deficiency.

As set forth at col. 5, ll. 40-43, the safety shield in Hausser is disclosed as being formed generically from a "thermoplastic material". The rejected claims of the subject application are

directed to a specific material, particularly a styrene block thermoplastic elastomer, which is absolutely not disclosed or suggested in Hausser. The advantages of this specific material are discussed extensively in Applicants' specification, such as at paras. [0033] - [0041]. Preservation of needle sharpness and improved sterilization are some of the obtained benefits of the claimed material and this material is not at all obvious from Hausser. It is respectfully submitted that claims 9-10, 26-27, 36-37, 48-49 and 58-59 each provide additional bases of patentability beyond that discussed above and are each, in turn, patentable over Baldwin et al., De Luca and Hausser, each taken alone or in combination.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



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